

Remarks/Arguments:

Double Patenting Rejection

Claims 9, 11, 12, 15, 29-46, 48, 49, 56, 62, 70, 87 and 88 stand rejected under the ground of nonstatutory obviousness-type double patenting as unpatentable over claims 1-24 of U.S. Patent No. 6,652,580 ("the '580 patent" in view of U.S. Patent No. 2,030,791 ("the '791 patent"). Applicants respectfully traverse this rejection.

Independent claim 9 is directed to an endovascular graft for treating vasculature, comprising:

a graft component including a first leg portion and a second leg portion, the first leg portion being attached along its length to the second leg portion, the graft component having an opening and a plurality of structures extending longitudinally beyond the opening, the opening having an opening circumference;

an expandable frame;

an attaching structure that attaches the expandable frame to the graft component by engaging at least one of the plurality of structures extending longitudinally beyond the opening; and

an anchoring structure that anchors the expandable frame to the lumen wall;

wherein the expandable frame is longitudinally separated from the graft component;

wherein the attaching structure attaches the expandable frame to the graft component at discrete locations on the graft component so that less than an entirety of a graft circumference is affixed to the attaching structure and wherein the opening of the graft component lacks other structure supporting a totality of the opening circumference; and

wherein at least one of the plurality of structures extending beyond the opening is in the form of a tab which is folded over a portion of the attaching structure.

The Office Action acknowledges that the '580 patent "does not specifically disclose the tabs as folded over to attach to the attaching structure." The Office Action cites to the '791 patent for the teaching that "a folding of tabs to secure to members is well known in the art."

Applicants respectfully contend that the combination of the '791 patent with the '580 patent is improper because the '791 patent is non-analogous.

To rely on a reference under 35 U.S.C. § 103, the reference must be "analogous prior art." MPEP § 2141(a)(I). The MPEP states that "prior art can be either in the field of applicant's endeavor or be reasonably pertinent to the particular problem with which the applicant was concerned." See MPEP § 2141(II)(A)(1) (emphasis added). A "reasonably pertinent" reference is "one which, because of the matter with which it deals, logically would have commended itself to an inventor's attention in considering his or her invention as a whole." MPEP § 2141(a)(I).

As noted above, independent claim 9 of the present application is directed to an endovascular graft for treating vasculature. The '791 patent is directed to "improvements in braces or suspenders." See the '791 patent at column 1, lines 1-2. Notably, the '791 patent is directed to a pair of suspenders for external use, while the present invention and the '580 patent both relate to stent-graft structures which are to be implanted within a human body. The '791 patent fails to disclose or suggest that the structures it recites are suitable for implantation in the human body. Accordingly, Applicants respectfully submits that the '791 reference is not within Applicant's field of endeavor.

Further, because the device of claim 9 is to be implanted, it must be designed and constructed with awareness of how the device may impact the human anatomy. Such considerations may include, for example, "a minimized delivery profile, easier catheterization..., and accurate deployment [of the stent components], and anchoring of the neck portion [of the stent] without disrupting cross-blow flow." See the original application at paragraph 0014. Correspondingly, one skilled in the art of implantable stent-grafts would not look to external clothing devices as such may have an adverse effect when implanted such as, for example, undesired occlusion or clotting. As noted above, the '791 patent deals with the matter of improving suspenders intended for external use. Accordingly, Applicants respectfully submit that the '791 patent is not reasonably pertinent to the particular problem with which the inventor was concerned.

Applicants respectfully submit that the '791 patent is not analogous prior art to the present invention. Accordingly, Applicants respectfully submit that the '791 patent cannot be combined with the '580 patent to reject the present claims. Therefore, Applicants respectfully request that this rejection be withdrawn.

Furthermore, Applicants respectfully submit that no reason to modify the reference teachings has been provided as required by the Supreme Court in KSR International Co. v. Teleflex Inc., 82 USPQ2d 1385 (2007). As noted by the Supreme Court, "[r]ejections on obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness". A reason supporting a conclusion of obviousness is proper only "so long as it takes into account only knowledge which was within the level of ordinary skill in the art at the time the claimed invention was made and does not include knowledge gleaned only from applicant's disclosure." See MPEP § 2145(X)(A).

The Office Action indicates that the addition of tabs serves to "provide a secure attachment even when a pulling force is applied from below." The Office Action fails to provide any support in the prior art for this reason. Applicants respectfully submit that none of the cited references disclose or suggest the use of a folded tab to strengthen an attachment against a pulling force. Applicants respectfully submit that only Applicants' own disclosure attributes such a benefit to the use of tabs: "[b]y attaching the tab 47 to graft material by sutures 48 or other means, the strength of the bond between the attachment stent 40 and main body component 30 is defined by the strength of the graft material, a bond that can be stronger than just a few sutures...." See original application at paragraph 0097. Accordingly, Applicants respectfully submit that the Office Action relies on impermissible hindsight in combining the '580 patent and the '791 patent. Therefore, Applicants respectfully request that this rejection be withdrawn.

Finally, even if the references were properly combinable, the cited references fail to teach or suggest each limitation of the claimed invention. As noted above, independent claim 9 recites "an attaching structure that attaches the expandable frame to the graft component by engaging at least one of the plurality of structures extending longitudinally beyond the opening;... and wherein at least one of the plurality of structures extending beyond the opening is in the form of a tab which is folded over a portion of the attaching structure." The Office Action cites to Fig. 11 of the '580 patent as teaching tabs of the graft. Figure 11 of the '580 patent depicts fixation device 100 attaching directly to material extensions 111 of the trunk 40 of the stent-graft 92. Figure 11 fails to disclose an attaching structure securing the expandable frame to the graft, as disclosed in independent claim 9. Applicant acknowledges that Figure 10 discloses ties 110 which secure the fixation device 100 to the trunk 40 of the stent-graft 92. However, Figure 10 of the '580 patent depicts the ties 110 passing directly through holes in the

graft material in a perpendicular direction. Accordingly, Applicant submits that ties 110 would prevent the use of a tab that folds over a portion of the attaching structure, as disclosed in independent claim 9. Accordingly, Applicants respectfully submit that the cited references fail to disclose, teach, or suggest all of the features of independent claim 9. Therefore, Applicant respectfully requests that this rejection be withdrawn.

It is respectfully submitted that because the '791 patent is a non-analogous reference, there is no permissible basis for combining the cited references, and even if combined, the references fail to teach each limitation of the claimed invention, the claims are not obvious in view of the combination of the '580 patent and the '791 patent. Withdrawal of the double patenting rejection is respectfully requested.

Claim Rejections Under 35 U.S.C. § 103

Claims 9, 11, 12, 15, 29-46, 48, 49, 56, 62, 70, 87 and 88 stand rejected under 35 U.S.C. §103 as unpatentable over the '580 patent in view of the '791 patent. Applicants respectfully traverse this rejection.

The Office Action provides no further basis for support of this rejection beyond that set forth in the double patenting rejection. As explained above, the '791 patent is a non-analogous reference, there is no permissible basis for combining the cited references, and even if combined, the references fail to teach each limitation of the claimed invention. Accordingly, Applicants respectfully submit that the claims are not obvious in view of the combination of the '580 patent and the '791 patent. Withdrawal of this rejection under 35 U.S.C. §103 is respectfully requested.

Claims 9, 11, 12, 15, 29-46, 48, 49, 56, 62, 70, 87, and 88 stand rejected under 35 U.S.C. § 103 as unpatentable over U.S. Pat. No. 6,280,466 to Kugler et al. ("Kugler") in view of U.S. Pat. No. 7,090,693 to Chobotov et al. ("Chobotov") further in view of the '791 patent. Applicants respectfully traverse this rejection.

"To establish a *prima facie* case of obviousness, ... the prior art reference (or references when combined) must teach or suggest all the claim limitations." M.P.E.P. §2143. Additionally, as set forth by the Supreme Court in KSR Int'l Co. v. Teleflex, Inc., No. 04-1350 (U.S. Apr. 30, 2007), it is necessary to identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the prior art elements in the manner claimed.

As noted above, independent claim 9 recites the feature of: "wherein the attaching structure attaches the expandable frame to the graft component at discrete locations on the graft component so that less than an entirety of a graft circumference is affixed to the attaching structure and wherein the opening of the graft component lacks other structure supporting a totality of the opening circumference." The absence of a structure surrounding the entirety of the graft circumference facilitates a smaller delivery profile and allow for greater compression of the stent 40. See the original application at paragraph 0087.

The Office Action cites to Figure 28 of Chobotov as disclosing the attaching structure. Applicants respectfully disagree. Figure 28 of Chobotov illustrates a connector member 283. The single connecting member 283 comprises a ring member 284 and connector elements 285. Ring member 284 as illustrated completely surrounds a totality of the opening circumference of graft body 280. Figure 29 of Chobotov further depicts a plurality of flaps 298 folded down over ring member 284. Chobotov discloses that "such flaps 298 have been folded over the substantial circumference of the ring member 284." Applicants respectfully submit that Chobotov discloses a single attaching structure 283 surrounding the circumference of graft body 280 adjacent the opening. Chobotov fails to disclose an attaching member "wherein the attaching structure attaches the expandable frame to the graft component at discrete locations on the graft component so that less than an entirety of a graft circumference is affixed to the attaching structure and wherein the opening of the graft component lacks other structure supporting a totality of the opening circumference," as recited in independent claim 9. Therefore, Applicants respectfully request that this rejection be withdrawn.

Claims 11, 12, 15, 29-46, 48, 49, 56, 62, 70, 87, and 88 each depend, either directly or indirectly, from independent claim 9. Accordingly, claims 11, 12, 15, 29-46, 48, 49, 56, 62, 70, 87, and 88 are allowable for at least the reasons that claim 9 is allowable. Therefore, Applicants respectfully request that this rejection to claims 11, 12, 15, 29-46, 48, 49, 56, 62, 70, 87, and 88 be withdrawn.

Conclusion

It is respectfully submitted that each of the pending claims is in condition for allowance. Early reconsideration and allowance of each of the pending claims are respectfully requested.

If the Examiner believes an interview, either personal or telephonic, will advance the prosecution of this matter, the Examiner is invited to contact the undersigned to arrange the same.

Respectfully submitted,



Joshua L. Cohen, Reg. No. 38,040
Glenn M. Massina, Reg. No. 40,081
Attorneys for Applicants

JLC/GMM/AJK/ams

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P.O. Box 980
Valley Forge, PA 19482
(610) 407-0700

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